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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,178	02/12/2002	David J. Eyre	7475-69889	5007

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EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/074,178	<b>Applicant(s)</b> EYRE ET AL.	
	<b>Examiner</b> Carolyn L Smith	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 18-24 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 18-24 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

Applicants' amendments and remarks, filed 8/16/04, are acknowledged. Amended claim 18 is acknowledged.

Applicants' arguments, filed 8/16/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 18-23 are herein under examination.

#### *Claims Rejected Under 35 USC § 112, first paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

#### LACK OF WRITTEN DESCRIPTION

Claims 18-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the invention was filed, had possession of the claimed invention.

This rejection is necessitated by amendment.

The specification, claims, and drawings as originally filed, do not appear to provide adequate support for the amended limitation in claim 18 that recites "wherein the scores are

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generated during nucleic acid amplification and wherein the scores are used, during nucleic acid amplification, to ascertain whether the nucleic acid is present in the sample”. The abstract states “Scores are obtained from various tests performed on the fluorescence data, and the scores are used to determine whether the nucleic acid is present in the sample.” However, this statement does not mention when the scores are obtained, such as during nucleic acid amplification. Also, on page 5, lines 3-5, the specification states “various tests are performed on the fluorescent data acquired during amplification, each of which test produces a numeric score. The scores are then used to determine a composite value, and a call is made based on that value.” While this section mentions that scores are produced, it fails to state that scores are generated and used *during* nucleic acid amplification. Instead, this section states that the fluorescent data were acquired during amplification. Because the introduction of “wherein the scores are generated during nucleic acid amplification and wherein the scores are used, during nucleic acid amplification, to ascertain whether the nucleic acid is present in the sample” lacks written basis for amended claim 18, filed on 8/16/04, it is considered NEW MATTER. Claims 19-23 are also rejected due to their direct or indirect dependency from amended claim 18. This rejection is necessitated by amendment.

### ***Claim Rejections – 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 18-23 is maintained under 35 U.S.C. 102(a) and 102(e)(2) as being anticipated by Schork et al. (P/N 6,291,182 B1).

This rejection is maintained and reiterated for reasons of record.

Due to the fact that the amended limitation of “wherein the scores are generated during nucleic acid amplification and wherein the scores are used, during nucleic acid amplification, to ascertain whether the nucleic acid is present in the sample” was considered to be NEW MATTER in amended claim 18 which consequently must be removed, this limitation was not addressed in the current prior art rejection.

Schork et al. disclose methods, software, and apparatus for determining the presence of a gene with a detectable trait in a genomic region (presence of a nucleic acid in a sample) (abstract). Schork et al. disclose using a Perkin Elmer 9600 Thermocycler to perform amplification of nucleic acids (col. 47, lines 1-6). Schork et al. disclose performing 40 cycles with 30 seconds at 95 degrees Celsius, 1 minute at 54 degrees Celsius and 30 seconds at 72 degrees Celsius (col. 47, lines 2-6) which represent rapid thermal cycling, as stated in instant claim 22. Schork et al. disclose using a fluorimeter and Picogreen (fluorescence) to determine quantities of amplification products (col. 47, lines 7-9). Schork et al. disclose the use of dideoxy terminator sequencing reactions (col. 47, lines 10-15) which represent a plurality of tests. Schork et al. disclose determination of sequences of amplification products (performing analysis

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routines) wherein the sequence data is evaluated using software designed to detect sites among the amplified products via different fluorescent molecules and by evaluating intensity ratios (col. 47, lines 10-28). Schork et al. disclose excluding artifacts due to background noise by comparing two DNA strands (col. 47, lines 29-34) which represents a signal-to-noise ratio test, as stated in instant claim 19. Schork et al. disclose using a variety of mathematic analysis tests, including Expectation-Maximization method (Maximum to Baseline Comparison Test) (col. 2, line 6), Wilcoxon rank test (function ordering test) (col. 2, line 62), Kolmogorov-Smirnov test (efficiency test using normal distribution) (col. 2, line 65), chi-square test (confidence interval test) (col. 2, line 50), and nonparametric tests (Last Rise Test) (Fig. 24). Schork et al. disclose performing linkage analysis based upon establishing a correlation between transmission of genetic markers and that of a specific trait throughout generations within a family and statistical methods for determination of the likelihood that the marker and trait are segregating independently (col. 18, lines 39-64) which represents a type of Channel Consistency Test where the channel consistency is represented by the consistent flow (presence) or lack thereof of the marker and trait transmission throughout generations.

Thus, Schork et al. anticipate the limitations in claims 18-23.

Applicants state that Schork et al. do not describe “a fluorimeter for detecting fluorescence during amplification of the nucleic acid” as required by claim 18. This statement is found unpersuasive for various reasons discussed below. Applicants state that Schork et al. disclose a fluorimeter and Picogreen which are used to determine quantities of amplification products “after amplification is complete”. Applicants state Shork et al. disclose a fluorescence

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measurement that is done “after amplification” of the nucleic acid. The broadest reasonable interpretation of the claim language “amplification of the nucleic acid” includes a broad process of amplification containing many steps which were never clearly defined by Applicants as to when it begins or ends. The end portion of this process includes the actual presence of amplified products which are then detected via fluorescence using a fluorimeter by Schork et al. Because the amplification process was not clearly defined by Applicants, it has been reasonably interpreted to include many steps, including steps involving amplified products. In addition, while the features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function (MPEP 2114). It is believed that the functional limitation of the fluorimeter “for detecting fluorescence during amplification of the nucleic acid” is adequately disclosed by the Schork et al. fluorimeter for the reasons described above. It is further noted in Example 17 of the Schork et al. patent, PCR cycles were used with components containing fluorescent ddNTPs (col. 59, lines 18-37) which represents “fluorescence during amplification of the nucleic acid” in yet another interpretation of this limitation in claim 18.

Applicants state a limitation was added to amended claim 18 to clarify that the scores are generated and used during amplification. The addition of this limitation to overcome the prior art rejection is found unpersuasive as the amended portion is considered to be NEW MATTER for failure to be supported by the specification, claims, or drawings, as originally filed.

### ***Conclusion***

No claim is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.



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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

October 18, 2004

*Ardin H. Marschel* 10/19/04  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER